IBUPROFEN- ibuprofen capsule, liquid filled AAFES/Your Military Exchanges

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt) *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - minor pain of arthritis
 - toothache
 - backache
 - the common cold
 - menstrual cramps
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug

- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over:
 - take 1 capsule every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 capsule, 2 capsules may be used
 - do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- each capsule contains: potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

Inactive ingredients

FD&C blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to The Active Ingredient of Advil® Liqui-Gels®†

Ibuprofen

IBUPROFEN 200 mg (NSAID)

Pain Reliever/Fever Reducer

Softgels**

(**Liquid Filled Capsules)

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil® Liqui-Gel®.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTER SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Manfactured For Your Military Exchanges

Distributed by:

PL Developments

Product Label



This product is not manufactured or distributed by Pfizer

OPENED OR IF PRINTED SAFETY SEAL UNDER CAP

TAMPER EVIDENT: DO NOT USE IF CARTON

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I-877-753-3935 Monday-Friday 9AM-5PM EST Consumer Healthcare, distributor of Advil® Liqui-Gels®

20

Questions or comments?

hydroxide, purified water, sorbitan, sorbitol

EXCHANGE SELECT Ibuprofen 200 mg Softgels

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55301-199

Route of Administration ORAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients		
ngth		

WATER (UNII: 059QF0KO0R)

SORBITOL (UNII: 506T60A25R)

SORBITAN (UNII: 6092ICV9RU)

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	IB200	
Contains				

Packaging	ckaging			
# Item Cod	e Package Description	Marketing Start Date	Marketing End Date	
1 NDC:55301- 199-20	1 in 1 BOX	06/30/2017	12/27/2024	
1	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2 NDC:55301- 199-80	1 in 1 BOX	06/30/2017	12/27/2024	
2	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing In	ormation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	06/30/2017	12/27/2024

Labeler - AAFES/Your Military Exchanges (001695568)

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